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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Thomas J. Borody

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ATLANTA, GA 30309-3915

EXAMINER

HAWTHORNE, OPHELIA ALTHEA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,258	Applicant(s) BORODY, THOMAS J.	
	Examiner OPHELIA HAWTHORNE	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 21, 23 - 24 & 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 21, 23 - 24 & 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendment/argument filed on 06/ 30/08. Currently, claims 1 – 21, 23 - 24, & 28 are pending in the instant application. Claims 22 & 25 – 27 are cancelled.

Response to Arguments

Applicant's arguments with respect to claims 1 –27 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1– 21, 23 –24 & 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hickle (US 2004/0129273 A1)** in view of **Albertelli (US 2005/0165304 A1)**.

Regarding claim 1, Hickle substantially discloses a bite block (**50, Fig. 3**) & **[0005]** comprising a generally annular body (**60, Fig. 3**) & **([0028], line 15)** adapted to be inserted into the mouth of a patient so as to maintain the upper and lower teeth of the patient in a spaced apart relationship **([0028], lines 1 – 6)** and define an endoscopic passage (**51, Fig. 3**) for introduction of an endoscope into the oral cavity **([0028], lines 1 – 4)** of the patient, the bite block (**50**) including a gas delivery passage (**63, Fig. 5**) for delivery of a gas (**i.e. oxygen**) & **([0041], lines 35 – 36)** to the oral cavity of the patient; and a gas distribution manifold detachably engaged with the bite block **([0038, lines 10 – 11])**, the gas distribution manifold comprising: at least one inlet port (**66, Fig. 7**) for receiving gas from a gas supply; at least one nasal outlet port (**78, Fig. 7**) in fluid communication with the inlet port (**66**) and adapted so as to direct gas to or toward the nasal passages of the patient; and an oral outlet port (**78**) in fluid communication with the inlet port (**66**) and configured such that when the gas distribution manifold is engaged with the bite block the oral outlet port is in fluid communication with the gas delivery passage.

Hickle substantially described the invention as claimed except for an attachment means for attaching the manifold to the patient so as to hold the manifold in position on the patient when the manifold is disengaged from the bite block; and when the gas

Art Unit: 3772

distribution manifold is disengaged from the bite block and the bite block is removed from the mouth of the patient the oral outlet port is adapted to direct gas over or toward the mouth of the patient.

However, Albertelli teaches a ventilation apparatus (**Fig. 9**) comprising a gas manifold (**100**) connected to a mouthpiece (**where element 10 is located**) via tubing **63**, a nasal mask (**60, Fig. 8**) via **61** as well as to a primer (**80, Fig. 9**) that produces a flow of air towards the mask same **[0060], lines 11 – 12)**. In the event that the mouthpiece (**where element 10 is located**) is disengaged from the gas distribution (the tubing are detachable, refer to Fig. 7) manifold (**100**), the primer (**80**) is adapted to direct gas over or toward the mouth of the patient (**[0060], lines 11 – 12)**. At the time of the invention, it would have been an obvious matter of design choice to provide an attachment means for attaching the manifold to the patient. The provision of an attachment means on the gas manifold , instead of on the bite block as shown by Hickle does not provide any unobvious result, and therefore, is not patentable over prior art.

Regarding claim 2, Hickle discloses at least one nasal port comprising a pair of apertures (**78, Fig. 7**) arranged such that gas flowing from the apertures is directed toward the patient's nostrils from a position below the nose of the patient (**[0039], lines 8 – 11)**.

Regarding claim 3, Hickle discloses the gas distribution manifold further includes a pair of tubular portions each adapted to extend at least partly into each nostril of the patient and defining two nasal outlet ports (**[0031], lines 1 – 8)**.

Regarding claim 4, Hickle discloses at least one nasal port comprising a single elongate aperture **(76, Fig. 7)**, the single elongate aperture extending laterally to the patient in use such that gas is delivered to both nostrils of the patient **(as shown in Fig. 7)**.

Regarding claim 5, Hickle discloses the oral outlet port **(78)** is a generally elongate aperture extending laterally relative to the patient in use.

Regarding claim 6, Hickle discloses the gas distribution manifold is detachably engaged with the bite block **([0038], lines 10 – 11)** by at least one frangible portion **([0039], lines 14 – 17)** extending between the bite block and the gas distribution manifold.

Regarding claim 7, Hickle disclose the bite block and the gas distribution manifold each further include respective cooperating engagement means configured such that the gas distribution manifold is detachably and attachably engageable with the bite block **([0038], lines 1 – 4)**.

Regarding claim 8, Hickle discloses the respective cooperating engagement means comprise compliant interlocking formations integrally formed with the gas distribution manifold and the bite block **([0039], lines 14 – 17)**.

Regarding claim 9, Hickle discloses the gas delivery passage comprising a first portion which is integrally formed with the annular body and defines a gas flow passage **(51, Fig. 3)** between the oral cavity and a front region of the annular body, and a second portion **(52, Fig. 5)** which provides a connection between the oral outlet port and the first portion, the second portion **(52)** having a distal end adapted to engage with the oral

outlet port to provide gas communication between the oral outlet port and the gas delivery passage.

Regarding claim 10, Hickle discloses the gas delivery passage is of slot shape in cross-section with the longitudinal axis of the slot shape extending transverse to the axis of the annular body (**Fig. 5**).

Regarding claim 11, Hickle disclose the gas delivery passage is integrally formed with the annular body and arranged such that when in use, the gas delivery passage is positioned superiorly to the endoscopic passage (**Fig. 5**).

Regarding claim 12, Hickle discloses the gas delivery passage terminates in a rearward facing opening which is arranged so as to deliver gas toward the rear of the oral cavity (**Fig. 5**).

Regarding claim 13, Hickle discloses the gas distribution manifold further includes a tubular connector (**98, Fig. 4**) extending from the inlet port, the connector having a distal end engageable with a gas supply conduit.

Regarding claim 14, Hickle discloses at least one obturator engagement formation integrally formed with the bite block, wherein the at least one obturator engagement formation provides an attachment point for an obturator member, the obturator member adapted to be used for depressing a patient's tongue to thereby provide improved access to the pharynx of the patient **[0036]**.

Regarding claim 15, Hickle substantially described the invention as claimed, see rejection to claim 1 above; except for the endoscopic passage has a diameter of at least 20 mm so as to allow the passage of a 60Fr dilator there through. In addition,

Art Unit: 3772

Hickle discloses a bite portion **(50, Fig. 3)** may be constructed with any suitable dimensions, where the bit portions may be large for scopes and tubes **[0028]**.

Therefore, it would have been obvious to one of ordinary skill in the art to construct a bit block with dimensions large enough to accommodate large medical devices, as for example, endoscopes.

Regarding claim 16, Hickle discloses an outer surface of the annular body (60) includes a contact portion **([0028], lines 11 – 15)** adapted to be engaged by the teeth of the patient when the annular body is operatively positioned within the mouth of the patient.

Regarding claim 17, Hickle discloses a cushioning member is affixed to the contact portion **([0028], lines 15 – 18)** so as to distribute the load imparted to the bite block by the patient's teeth.

Regarding claim 18, Hickle disclose the bite block in includes an outer peripheral flange **(64, Fig. 3)** adapted to overlies the lips of the patient.

Regarding claim 19, Hickle substantially described the invention as claimed, see rejection to claim 1 above, except for the bite block and the gas distribution manifold are formed from a resilient polymeric material. In addition, Hickle discloses the bite block is constructed from a flexible material by injection molding **([0027], lines 1 – 6)** is an equivalent structure known in the art. Therefore, because these structures were art-recognized equivalents at the time the invention was made, one of ordinary skill would have found it obvious to substitute one for another.

Regarding claim 20, Hickle substantially described the invention as claimed, see rejection to claim 1 above, except for the gas distribution manifold further includes an attachment means for securing the gas distribution manifold to the patient.

However, Albertelli teaches a ventilation apparatus (**Fig. 9**) comprising a gas manifold (**100**) connected to a mouthpiece (**where element 10 is located**) via tubing **63**, a nasal mask (**60, Fig. 8**) via **61** as well as to a primer (**80, Fig. 9**) that produces a flow of air towards the mask same **[0060], lines 11 – 12)**. In the event that the mouthpiece (**where element 10 is located**) is disengaged from the gas distribution (the tubing are detachable, refer to Fig. 7) manifold (**100**), the primer (**80**) is adapted to direct gas over or toward the mouth of the patient (**[0060], lines 11 – 12)**. At the time of the invention, it would have been an obvious matter of design choice to provide an attachment means for attaching the manifold to the patient. The provision of an attachment means on the gas manifold, instead of on the bite block as shown by Hickle does not provide any unobvious result, and therefore, is not patentable over prior art.

Regarding claim 21, Hickle discloses a gas distribution manifold for providing a gas to a patient, the gas distribution manifold comprising: at least one inlet port (**66**) for receiving a gas from a gas supply; at least one nasal outlet port (**76**) in fluid communication with the inlet port (**66**) and adapted to direct gas to the nasal passages of the patient; and an oral outlet port (**78**) in fluid communication with the inlet port (**66**) and adapted to direct gas over or toward the mouth of the patient; the gas distribution manifold being detachably engageable with a bite block via clip **67** having a gas delivery passage for delivery of a gas to the oral cavity of the patient; wherein the oral outlet port

Art Unit: 3772

(78) is configured such that when the gas distribution manifold is engaged with the bite block (50) the oral outlet port (78) is in fluid communication with the gas delivery passage if the bite block.

Hickle substantially described the invention as claimed, except for attachment means for attaching the manifold to the patient so as to hold the manifold in position on the patient when the manifold is disengaged from the bite block and when the gas distribution manifold is disengaged from the bite block and the bite block is removed from the mouth of the patient the oral outlet port is adapted to direct gas over or toward the mouth of the patient.

However, Albertelli teaches a ventilation apparatus (**Fig. 9**) comprising a gas manifold (**100**) connected to a mouthpiece (**where element 10 is located**) via tubing **63**, a nasal mask (**60, Fig. 8**) via **61** as well as to a primer (**80, Fig. 9**) that produces a flow of air towards the mask same **[0060], lines 11 – 12)**. In the event that the mouthpiece (**where element 10 is located**) is disengaged from the gas distribution (the tubing are detachable, refer to Fig. 7) manifold (**100**), the primer (**80**) is adapted to direct gas over or toward the mouth of the patient (**[0060], lines 11 – 12)**. At the time of the invention, it would have been an obvious matter of design choice to provide an attachment means for attaching the manifold to the patient. The provision of an attachment means on the gas manifold, instead of on the bite block as shown by Hickle does not provide any unobvious result, and therefore, is not patentable over prior art.

Regarding claim 23, Hickle discloses the gas is delivered to the patient during recovery from anaesthesia (**[0041], lines 1 – 2)**.

Regarding claim 24, Hickle discloses the gas is an oxygen rich gas **([0041], lines 36 – 36)**.

Regarding claim 28, Hickle discloses a method of delivering gas to a patient during and after an endoscopic procedure **[0040] & [0041]** using apparatus comprising a gas distribution manifold having a gas inlet port **(66)**, a nasal gas outlet port **(76)**, an oral gas outlet port **(78)**, and a annular bite block **(50)** detachably connected to the manifold via clip 67, the method comprising the steps of: attaching the apparatus to the patient using the attachment means with the bite block located in the mouth of the patient; supplying gas to the patient via the gas inlet port, the nasal gas outlet port, and the oral gas outlet port; performing an endoscopic procedure on the patient while continuing to supply gas to the patient; removing the bite block from the patient and detaching the bite block from the manifold while leaving the manifold attached to the patient; and performing one or more further procedures on the patient or allowing the patient to recover while continuing to supply gas to the patient via the nasal gas outlet port and the oral gas outlet port.

Hickle teaches all of the elements of the claimed invention; therefore the steps of attaching the apparatus to the patient using the attachment means with the bite block located in the mouth of the patient; supplying gas to the patient via the gas inlet port, the nasal gas outlet port, and the oral gas outlet port; performing an endoscopic procedure on the patient while continuing to supply gas to the patient; removing the bite block from the patient and detaching the bite block from the manifold while leaving the manifold attached to the patient; and performing one or more further procedures on the patient or

Art Unit: 3772

allowing the patient to recover while continuing to supply gas to the patient via the nasal gas outlet port and the oral gas outlet port would be obvious to one of ordinary skill in the art because they would have resulted from the use of Hickie.

Hickie substantially described the invention as claimed, except for and attachment means for attaching the manifold to the patient.

However, Albertelli teaches a ventilation apparatus (**Fig. 9**) comprising a gas manifold (**100**) connected to a mouthpiece (**where element 10 is located**) via tubing **63**, a nasal mask (**60, Fig. 8**) via **61** as well as to a primer (**80, Fig. 9**) that produces a flow of air towards the mask same **[0060], lines 11 – 12**). In the event that the mouthpiece (**where element 10 is located**) is disengaged from the gas distribution (the tubing are detachable, refer to Fig. 7) manifold (**100**), the primer (**80**) is adapted to direct gas over or toward the mouth of the patient (**[0060], lines 11 – 12**). At the time of the invention, it would have been an obvious matter of design choice to provide an attachment means for attaching the manifold to the patient. The provision of an attachment means on the gas manifold, instead of on the bite block as shown by Hickie does not provide any unobvious result, and therefore, is not patentable over prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3772

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OPHELIA HAWTHORNE whose telephone number is (571)270-3860. The examiner can normally be reached on Monday - Friday, 7:30 AM - 5:00 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/568,258
Art Unit: 3772

Page 13

/Ophelia Hawthorne/
Examiner, Art Unit 3772

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